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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/455,486	12/06/1999	DANIEL E. AFAR	1703-011.US2	5189

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EXAMINER

NICKOL, GARY B

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/02/2002 16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/455,486

Applicant(s)

AFAR ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-18,20,21 and 24-48 is/are pending in the application.
- 4a) Of the above claim(s) 4-18,20,21 and 24-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 44-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>15</u> . | 6) <input type="checkbox"/> Other: _____ |

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Response to Amendment

The Amendment filed October 18, 2001 (Paper No. 14) in response to the Office Action of April 12, 2001 is acknowledged and has been entered. Claims 2-3, and 22-23 were cancelled. Claims 44-48 were added. Claims 4-18, 20-21, and 24-43 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 1 and 44-48 are pending and are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Specification

The specification remains objected for the reasons of record in Paper No. 11, pages 3-5. Applicants attempt to correct sequence disclosures by amending the specification to recite "portions" and or "same" (i.e. see tables on page 49) does not perfect the original objection. All sequence disclosures (whether they are portions or fragments of predisclosed sequences) are considered unique sequences and require separate identifiers, i.e. SEQ ID NO:s. Hence, applicant has not complied with the requirements of 37 CFR 1.821 through 1.825. Applicant must provide a computer readable form (CRF) copy of the sequence listing, an initial or substitute paper copy of the sequence listing, as well as any amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are

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the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e-f) or 1.825(b) or 1.825(d).

Rejections Maintained

Claim 1 remains rejected and new claims 44-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record in Paper No. 11, pages 6-11.

Applicants contend (Paper No. 14, pages 10-12) that the general teachings in the art (i.e. the cited references of Gura, Spitler, and Bellone *et al.*) are not sufficient to cast doubt on the credibility of the present invention because such teachings do not hold true for all potential anticancer vaccines. Applicants further argue that the references do not indicate that it would be impossible to utilize the appropriate immunogen to elicit an appropriate response. This argument has been considered but is not found persuasive. Applicant has argued and discussed the references individually without clearly addressing the combined teachings. That is, the state of the art with regards to the treatment of cancer, in general, and the immunotherapy of cancer is unpredictable. Thus, to simply state that applicant's claimed invention might be useful and is therefore not subject to the perceived unpredictability in the art, is without merit because applicant has not provided sufficient guidance and objective evidence that would reasonably exempt the claimed invention from the general teachings. Further, it must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is

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the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention.

With regards to the predictability of protein production, applicants argue (Paper No. 14, page 13) that the existence of high levels of mRNA is quite probative evidence that protein will be produced. Applicant further argue that protein is produced in all of the cited references except for Alberts *et al.* and that (page 14) all that is required is that sufficient levels of the protein be present to subject the tissue to immunological attack. These arguments have been considered but are not found persuasive. Again, applicant has argued the references individually without clearly addressing the combined teachings. Alberts *et al.* clearly teach that expression of mRNA does not dictate nor predict the translation of mRNA into polypeptide. Further, evidence that some amount of protein is actually produced does not necessarily mean that one of skill in the art would know how to use the protein in any predictable manner. Applicant has stated that the claims are directed to inducing an immunological response to prostate tissue expressing STEAP-2 polypeptide rather than providing a marker or target (top of page 13). This argument has been considered but is not found persuasive. First, as previously stated, the specification provides insufficient guidance and objective evidence that any vaccine composition comprising a STEAP-2 protein would effectively treat cancer with any predictability. Secondly, the preamble recitation of a composition for inducing an immunological response is merely suggestive of an intended use and is not given weight for purposes of comparing the claims with the state of the art. The claims are directed to the produce *per se*, an isolated protein. And while the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into claims. On the contrary, claims must be interpreted as

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broadly as their terms reasonably allow. See Ex parte Oetiker, 23 USPQ2d 1641 (BPAI, 1992).

Applicant is reminded that the claims define the subject matter of his invention and that the specification cannot be relied upon to read limitations into the claims. Thus, applicants arguments have not been found persuasive, and the rejection is maintained.

NEW REJECTIONS

Claims 44, 47-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' referral to the STEAP-2 cDNA deposit (PTA-311) on page 44 of the specification is an insufficient assurance that all of the conditions of 37 CFR sections 1.801 through 1.809 have been met. If the deposits were made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that the deposits have been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each State. Additionally, amendment of the specification to recite the date of the

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deposit and the complete name and address of the depository is required. Applicant is reminded that the American Type Culture Collection address has been rewritten as 10801 University Boulevard, Manassas, VA 20110-2209.

All other rejections and or objections are withdrawn.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol Ph.D.
Examiner
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GBN
December 31, 2001


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600